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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,439	02/23/2000	BERNHARD A. SABEL	10644-0001-2	9939

7590

07/09/2002

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT
1755 JEFFERSON DAVIS HIGHWAY
FOURTH FLOOR
ARLINGTON, VA 22202

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/445,439

Applicant(s)

SABEL ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The amendment filed 5/29/2002 has been entered. The specification has been amended as requested. Claims 88 and 101 have been amended.

Response to Arguments

Any previous rejection(s) which are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 88-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Canal (EP 486959) or Bernstein in view of Kreuter (WO 95/22963) and Jans (US 5,759,580), for the reasons set forth in the office action mailed 01/07/2002.

Applicant's arguments filed 05/29/2002 have been fully considered but they are not persuasive.

Applicant asserts that since Canal teaches the addition of an agent modifying the interface properties, this is contrary to the claimed particles which are "free of a surfactant coating" thus, Canal teaches away from the claimed invention.

This is not found persuasive because it is noted that the claimed particles are not "free of a surfactant" but are "free of a surfactant coating." The particles disclosed by Canal encompass such particles, since the methods of preparing the particles are the same as that claimed and do not include a method of coating the particles. The agent for modifying the interface is mixed with the polymer in a solvent and the particles are extruded or spray dried. This method would not form particles which are coated with a surfactant, see page 3. Canal teaches that the agent modifying the interface may be 0.1 % as compared to the polymer, clearly not an amount for coating the particles, see page 4, lines 27+. Further, Canal discloses that the agent for modifying the interface is used as a modulator of the solubility of the active agent, not as a coating for the particles, see page 4, lines 46+.

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In response to applicant's argument that Bernstein fails to disclose that the particles are for crossing the blood brain barrier (bbb), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant asserts that Bernstein fails to disclose that the particles contain a drug.

This is not found persuasive because Bernstein clearly discloses particles which contain a diagnostic agent, and the term "drug" is defined by applicant on page 12, line 22 of the specification to include "diagnostic agents." Bernstein also discloses that substances for nuclear medicine, etc. may be contained in the particles, which are clearly encompassed by the term "drug", see column 9, lines 21+.

Applicant further asserts that the stabilizers as claimed are not disclosed by Bernstein.

This is not found persuasive because, as set forth in the last office action, Bernstein discloses nanoparticles for *in vivo* use comprising hydrophobic stabilizers, e.g., triglyceride derivatives, etc., such as those claimed, as well as, 1,3-dipalmitoyl-2-succinylglycerol, which would be within the scope of a carboxylic acid of glycerol, (as claimed as a stabilizer).

Applicant asserts that Kreuter does not cure the deficiencies of the primary references because Kreuter discloses particles which are coated with a surfactant.

This is not found persuasive because Kreuter is only being relied upon to teach that various polymers are known as equivalents for nanoparticles used for *in vivo* drug delivery, not for teaching particles which may lack a surfactant coating, which is disclosed by Canal and Bernstein.

Applicant asserts that Bernstein is not concerned with crossing the bbb.

As set forth above, the "intended use" of a claimed composition (or method of making thereof) cannot be used as the sole basis to differentiate over the prior art.

Applicant asserts that Jans does not cure the deficiencies of the primary references because Jans does not teach the particular target system as claimed.

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This is not found persuasive because Jans is only relied upon to teach that a specific polysorbate, e.g., polysorbate 85, is known in the art for use in particle formulation for drug delivery and may be used in equivalent manner to other polysorbates, e.g., such as those disclosed by Canal.

Conclusion

No claims are allowed at this time.

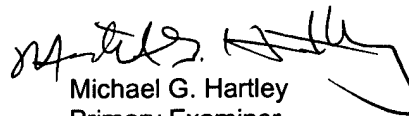
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
July 5, 2002